DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-214/S-013

Organon, Inc.
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Attention: Dori L. Glassner
Associate Director, Regulatory Affairs

Dear Ms. Glassner :

Please refer to your supplemental new drug application dated November 8, 2000, received November 9, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemuron (rocuronium bromide) Injection.

This "Changes Being Effected" supplemental new drug application provides for the change from pregnancy category “B” to “C” as requested by the Agency as well as inclusion of preclinical doses and multiple of the human dose for both the rat and rabbit studies. In addition, further labeling changes to the package insert include a revision of the solution color in the “Description” section, and revision of the reports of allergic reactions to include anaphylactic and anaphylactoid shock in the “Adverse Reactions” section.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 8, 2000).

Please submit the copies of final printed labeling (FPL) electronically, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20214/S-013." Approval of this submission by FDA is not required before the labeling is used.

Since this supplement and its FPL supercedes supplements S-008 and S-010, we understand that FPL for those supplements will not be received since it was never printed, and changes approved in those supplements will be incorporated into the FPL for this supplement.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research